



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



October 27, 1993

Food and Drug Administration
Washington DC 20204

Nelida Bravo
Manager
Regulatory Affairs
Elf Sanofi, Inc.
101 Park Avenue
New York, New York 10178

Dear Ms. Bravo:

This replies to your facsimile dated September 28, 1993 in which you request information pertaining to the requirements for ingredient labeling on cosmetic products offered as a gift, a sample or as a "gift-with-purchase."

The sole legal authority for cosmetic ingredient labeling is the Fair Packaging and Labeling Act (FPLA). Cosmetic ingredient labeling is required only for retail packaging and only for commodities designed for retail purchase. This excludes free samples and free gifts. Therefore, cosmetic products offered solely as free gifts or as free samples are not required to bear ingredient labeling. However, the labels for such products are still subject to the label requirements under the Federal Food, Drug and Cosmetic Act (FD&C Act) and must bear label information which includes the net quantity of contents declaration, the name and place of business of the manufacturer, packer or distributor and appropriate or required warning statements.

In the case of "gift-with-purchase," we have stated that the "gift" must bear a complete ingredient declaration on the label of the package in accordance with the requirements of 21 CFR §701.3. The "gift" is not a free gift per se, but can only be obtained by consumers who purchase the product to which the gift is attached.

We trust that this information is helpful.

Sincerely yours,

Allen R. Halper
Assistant to the Director
Division of Programs and
Enforcement Policy
Office of Cosmetics and Colors
Center for Food Safety
and Applied Nutrition